

EPA REGISTRATION
FILE JACKET
REG #5905-591

Material Sent for Data Extraction

Reg. # 5905-LOR

Description: _____

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 2/5/13

☐ Notification Dated _____

☒ New CSF(s) Dated 10/1/12

☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Autumn Metzger

Phone: 305-5314 Division: RD - IRB

Date: 2/5/13



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Chemical Safety and Pollution Prevention
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

5905-591

Date of Issuance:

FEB 05 2013

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Pro-Mate Merit 0.2% with Turf
Fertilizer

Name and Address of Registrant (include ZIP Code):

Helena Chemical Company
225 Schilling Boulevard, Suite 300
Collierville, TN 38017

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label change before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No 5905-591."

Signature of Approving Official:

Venus Eagle, Product Manager 01
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date:

FEB 05 2013

3. Submit one copy of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. If you have any questions, please contact Autumn Metzger at 703-305-5314 or metzger.autumn@epa.gov.

A stamped copy of the label is enclosed for your records.

Venus Eagle
Product Manager 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

FEB 05 2013

Under the Federal Insecticide, Fungicide
and Fumigant Act, As amended, for the
pesticide Registered under EPA Reg. No:

5905-591

Pro-Mate® Merit® 0.2% With Turf Fertilizer

For fertilization and listed insect control in turfgrass and landscape ornamentals and sod farms.

Fertilizer with MERIT® Insecticide.

Contains Merit® Insecticide

30 lbs. treats 8525 sq ft (0.2 Acre) at the 150 lbs product /acre - - LOW RATE (3.5 lbs/1,000 sq. ft.)

30 lbs. treats 6660 sq ft (0.15 Acre) at the 200 lbs product /acre - HIGH RATE (4.5 lbs/1,000 sq. ft.)

Net Wt. 30 lbs (13.61 Kg)

Treats up to 8525 sq ft

40 lbs. treats 11,362 sq ft (0.265 Acre) at the 150 lbs product /acre - LOW RATE (3.5 lbs/1,000 sq. ft.)

40 lbs. treats 8,880 sq ft (0.20 Acre) at the 200 lbs product /acre - HIGH RATE (4.5 lbs/1,000 sq. ft.)

Net Wt. 40 lbs. (18.145 Kg)

Treats up to 11,362 sq ft

50 lbs. treats 14,200 sq. ft. (0.33 acre) at the 150 lbs. product/acre - LOW RATE (3.5 lbs/1,000 sq. ft.)

50 lbs. treats 11,100 sq. ft. (0.25 acre) at the 200 lbs. product/acre - HIGH RATE (4.5 lbs/1,000 sq. ft.)

Net Wt. 50 lbs. (22.68 Kg.)

Treats Up To 14,200 Sq. Ft.

ACTIVE INGREDIENT:

Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-imidazolidinimine 0.2%

OTHER INGREDIENTS: 99.8%

TOTAL: 100.0%

**STOP - READ THE LABEL BEFORE USE.
KEEP OUT OF REACH OF CHILDREN.**

CAUTION

PRECAUCION AL USUARIO: Si usted no puede leer o entender inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

(TO THE USER: If you cannot read or understand English, do not use this product until the label has been fully explained to you.)

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information, in case of an emergency, call 800-424-9300.	
Note to Physician: No specific antidote is available. Treat the patient symptomatically.	

EPA Reg. No. 5905-xxx

EPA Est. No. _____

AD xxxxxx

NET WEIGHT: _____ lbs.

Filename: ProMate Merit 0.2% with TF (5905-LOR) 012313 CLN.doc

1

Manufactured for
Helena Chemical Company
225 Schilling Boulevard, Suite 300
Collierville, TN 38017

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Causes moderate eye irritation. Harmful if absorbed through skin or swallowed. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE):

WPS USES: *Applicators and Other Handlers who handle this product for any use covered by the Worker Protection Standard (40 CFR part 170) – in general, agricultural plant uses e.g., use in sod farms, must wear:*

- *Long-sleeved shirt and long pants*
- *Chemical resistant gloves made of any waterproof material such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride (PVC) or viton. If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.*
- *Shoes plus socks*

Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Non-WPS USES: *Applicators and other handlers who handle this product for any use NOT covered by the Worker Protection Standard (40 CFR part 170) – in general, only agricultural plant uses are covered by the WPS, must wear:*

- *Long-sleeved shirt and long pants*
- *Chemical-resistant gloves (such as Natural Rubber, Selection Category A)*
- *Shoes plus socks*

USER SAFETY RECOMMENDATION

Users should:

- *Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.*
- *Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.*
- *Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.*

ENVIRONMENTAL HAZARDS

This product is highly toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

This chemical demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks

Do not formulate this product into other end-use products.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Keep children and pets off treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty bag into application equipment. Dispose of empty bag in a sanitary landfill or by incineration or if allowed by the state and local authorities, by burning. If burned, stay out of smoke.

Handle and open container in a manner as to prevent spillage. If material is spilled for any reason or cause, carefully contain any spilled material to prevent non-target contamination. Do not walk through spilled material and dispose of as directed for pesticides above. Refer to Precautionary Statements on label for hazards associated with the handling of this material. In spill or leak incidents, keep unauthorized people away.

APPLICATION TO TURFGRASS

The use of this product will provide plant nutrients as well as providing control of selected insect pests. Pro-Mate Merit 0.2% with Turf Fertilizer can be used for the control of the following listed soil inhabiting pests of turfgrass; northern & southern masked chafers, *Cyclocephala borealis*, *C. immaculata*, and/or *C. lurida*; Asiatic garden beetle, *Maladera castanea*; European chafer, *Rhizotrogus majalis*; Green June beetle, *Cotinus nitida*; May or June beetles, *Phyllophaga* spp.; Japanese beetle, *Popillia japonica*; Oriental beetle, *Anomala orientalis*; billbugs, *Sphenophorus* spp.; annual bluegrass weevil, *Listronotus maculicollis*. Black turfgrass ateniinus, *Ataenius spretulus*; *Aphodius* spp.; crane flies, *Tipula* spp., and mole crickets, *Scapteriscus* spp. Pro-Mate Merit 0.2% with Turf Fertilizer can be used as directed on turfgrass; in home lawns, business and office complexes, shopping complexes, multi-family residential complexes, golf courses, airports, cemeteries, parks, playgrounds, athletic fields and sod farms.

The active ingredient in Pro-Mate Merit 0.2% with Turf Fertilizer has sufficient residual activity so that applications can be made preceding the egg laying activity of the target pests. High levels of control can be achieved when applications are made preceding or during the egg laying period. The need for an application can be based on historical monitoring of the site, previous records or experiences, current season adult trapping or other methods. Optimum control will be achieved when applications are made prior to egg hatch of the target pest, followed by sufficient irrigation or rainfall to move the active ingredient through the thatch.

APPLICATION TO ORNAMENTALS

Pro-Mate Merit 0.2% with Turf Fertilizer can be used as a broadcast application on ornamentals in commercial and residential landscapes, as well as on landscaped areas of golf courses and other recreational areas. This is a systemic product, with the active ingredient being absorbed by the roots and translocated upward within the plant. Optimum control will be achieved when applications are followed by sufficient mechanical incorporation, irrigation or rainfall to place the active ingredient into the soil. Make application prior to anticipated pest infestation to achieve optimum levels of control.

RESTRICTIONS:

- Do not exceed a total of 200 lb of product (0.4 lb of active ingredient) per acre per year.
- Do not make applications when turfgrass areas are waterlogged or the soil is saturated with water. Adequate distribution of the active ingredient cannot be achieved when these conditions exist. The treated turf must be in such a condition that the rainfall or irrigation will penetrate vertically into the soil profile.
- Not for use in commercial greenhouses, or nurseries.
- Keep people and pets off treated area until dry

APPLICATION EQUIPMENT

Apply Pro-Mate Merit 0.2% with Turf Fertilizer uniformly over the area being treated with typical granular application equipment. Both drop-type and rotary-type spreaders may be used to apply Pro-Mate Merit 0.2% with Turf Fertilizer. Do not use spreaders which would apply the material in narrow, concentrated bands. Calibrate application equipment prior to use according to the manufacturer's directions. Check frequently to be sure equipment is working properly and distributing granules uniformly and accurately.

SPREADER SETTINGS FOR PRO-MATE MERIT 0.2% WITH TURF FERTILIZER

The following chart can be used as a guide in establishing an accurate rate of Pro-Mate Merit 0.2% with Turf Fertilizer. The suggested settings provide an application rate of 3.5 lb per 1000 sq ft, or 150 lb per acre. Application rates will vary dependent upon speed, equipment wear and condition of spreader. Carefully calibrate all equipment used prior to commercial use of this product.

SPREADER	SPEED (mph)	SETTINGS
		3.5 lb/ 1000 sq. ft or 150 lbs./A
Cyclone Way	3	
Earthway 2400		
Gandy Turf Tender 24"	3	
Gandy Turf Tender 42"	3	
Lely	4.5	
Lesco Broadcast	3	
PSB Prizelawn CBR-III	3	
Scott's Proturf R-8A	3	
Scott's Proturf SR-2000	3	
Scott's Handy Green	3	
Scott's Accupro	3	
Spyker	3	
Vicon Model 402	4.5	

(Spreaders and settings will vary depending on markets, spreader availability and fertilizer blends used)

APPLICATION RATES		
CROP	PEST	DOSAGE PROMATE MERIT + TURF FERTILIZER
Turf Grasses	Annual bluegrass weevil Billbugs Crane flies Larvae of white grubs, for example: Aphodius sp. Japanese beetle Asiatic garden beetle Northern masked chafer Black turfgrass ataenius Oriental beetle European chafer Phyllophaga spp. Green June beetle Southern masked chafer	150 to 200 lb per acre or 3.5 to 4.5 lb per 1000 sq ft
	For optimum control, make application prior to egg hatch of the target pest. Be sure to read "APPLICATION EQUIPMENT" Section of this label.	
	Mole crickets Chinch bugs (suppression)	200 lb per acre or 4.5 lb per 1000 sq ft
	For suppression of chinch bugs, make application prior to the hatching of the first instar nymphs. For control of mole crickets make application within one week of the peak egg hatch period. If application is not made prior to egg hatch, and adults or large nymphs are present and actively tunneling, apply Pro-Mate Merit 0.2% with Turf Fertilizer in combination with a remedial insecticide to minimize damage to turf.	
	Consult your local State Agricultural Experiment Station or State Extension Turf Specialists for more specific information regarding timing of application. Irrigate if rainfall does not occur within 24 hours after application to move the active ingredient through the thatch. On golf courses, irrigate treated areas following application.	
Restrictions for Turf Grasses: <ul style="list-style-type: none">Do not apply more than 200 lb (0.4 lb of active ingredient) per acre per year or 4.5 lbs per 1000 sq. ft. per year.Do not mow turf or lawn area until after irrigation or rainfall has occurred so that uniformity of application will not be affected.		

APPLICATION RATES FOR USE ON ORNAMENTALS		
CROP	PEST	DOSAGE PROMATE MERIT + TURF FERTILIZER
Landscape Plantings Including: Trees, Shrubs, Evergreens, Flowers, Foliage, Plants, Ground Covers	White grub larvae For example: Japanese beetle larvae, chafers, Phyllophaga spp. Asiatic garden beetle, Oriental beetle	3.5 to 4.5 lb per 1000 sq ft
<p>Apply as a broadcast treatment. Prior to application, remove black plastic or other weed barrier material that will not permit water permeability.</p> <p>Mechanical incorporation, irrigation or rainfall must occur within 24 hours after application to move the active ingredient into soil.</p> <p>Refer to label sections on application equipment and spreader settings.</p> <p>Restrictions for Ornamentals:</p> <ul style="list-style-type: none"> Do not allow runoff or puddling of irrigation water following application. Do not apply Pro-Mate Merit 0.2% with Turf Fertilizer to areas which are water-logged or saturated, which will not allow penetration into the root zone of the plant. Do not apply more than 4.5 lbs of product per 1000 sq. ft. per year. Do not apply to vegetable gardens. Do not harvest or consume fruits or nuts from trees that have been treated within one year (365 days). 		

CONDITIONS OF SALE - LIMITED WARRANTY AND LIMITATIONS OF LIABILITY AND REMEDIES

Read the Conditions of Sale - Warranty and Limitations of Liability and Remedies before using this product. If the terms are not acceptable, return the product, unopened, and the full purchase price will be refunded.

The directions on this label are believed to be reliable and must be followed carefully. Insufficient control of pests and/or injury to the crop to which the product is applied may result from the occurrence of extraordinary or unusual weather conditions or the failure to follow the label directions or good application practices, all of which are beyond the control of Helena Chemical Company (the "Company") or seller. In addition, failure to follow label directions may cause injury to crops, animals, man or the environment. The Company warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose referred to in the directions for use subject to the factors noted above which are beyond the control of the Company. The Company makes no other warranties or representations of any kind, express or implied, concerning the product, including no implied warranty of merchantability or fitness for any particular purpose, and no such warranty shall be implied by law.

To the extent consistent with applicable law, the exclusive remedy against the Company for any cause of action relating to the handling or use of this product shall be limited to, at Helena Chemical Company's election, one of the following:

1. Refund of the purchase price paid by buyer or user for product bought, or
2. Replacement of the product used

To the extent consistent with applicable law, the Company shall not be liable and any and all claims against the Company are waived for special, indirect, incidental, or consequential damages or expense of any nature, including, but not limited to, loss of profits or income. The Company and the seller offer this product and the buyer and user accept it, subject to the foregoing conditions of sale and limitation of warranty, liability and remedies.

Merit® is a registered trademark of Bayer.

[For placement under Fertilizer Guarantee Section]

Fertilizer Analysis: X-X-X

Information regarding the contents and levels of metals in this product is available on the Internet at HYPERLINK <http://www.aapfco.org/metals.htm>.

For Florida:

FLORIDA APPLICATIONS: For use on golf courses or other athletic turf in FL, we recommend you follow SL191, "Recommendations for N, P, K & Mg for Golf Course and Athletic Field Fertilization Based on Mehlich I Extractant", available on the internet at <http://edis.ifas.ufl.edu/SS404> or "Best Management Practices for the Enhancement of Environmental Quality on Florida Golf Courses" at HYPERLINK "<http://www.flaes.org/pdf/glfbmp07.pdf> "

FLORIDA APPLICATIONS: For commercial application to urban turf or lawns in FL, we recommend you follow the Best Management Practices for Protection of Water Resources in Florida, June 2002, Florida Green Industries, available at HYPERLINK "http://www.flaes.org/pdf/BMP_Book_final.pdf".



RE: 5905-LOR
Washburn, Bill to: Autumn Metzger

01/24/2013 09:44 AM

Autumn,

Revised as requested.

Thanks,

Bill Washburn
Helena Chemical Company
901-752-4420

From: Metzger.Autumn@epamail.epa.gov [mailto:Metzger.Autumn@epamail.epa.gov]
Sent: Wednesday, January 23, 2013 2:56 PM
To: Washburn, Bill
Subject: RE: 5905-LOR

only a couple of comments:

page 2 the precautionary statement should have as the second sentence read: "Harmful if absorbed through the skin or swallowed."

page 6, add "To the extent consistent with applicable law" in the front of the sentence that reads "The exclusive remedy against the company for any cause..."

Autumn Metzger
Biologist
U.S. Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (7505P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Tel: 703 305-5314
Fax: 703 308-5433
Email: metzger.autumn@epa.gov

▼ "Washburn, Bill" ---01/23/2013 10:23:02 AM---Autumn, I have attached the revised Pro-Mate Merit 0.2% With Turf Fertilizer label based on the Agen

From: "Washburn, Bill" <WashburnB@helenachemical.com>
To: Autumn Metzger/DC/USEPA/US@EPA
Date: 01/23/2013 10:23 AM
Subject: RE: 5905-LOR



RE: 5905-LOR
Washburn, Bill to: Autumn Metzger

01/23/2013 10:23 AM

Autumn,

I have attached the revised Pro-Mate Merit 0.2% With Turf Fertilizer label based on the Agency comments and telephone conversation yesterday morning.

As agreed, I have left "sod farms" on the label in hopes that Syngenta's Tech amendment gets approved before the due date for this PRIA action.

Any last minute changes can be addressed immediately if needed.

Thanks for your help.

Regards,

Bill Washburn

Registration Specialist

Helena Chemical Company

901-752-4420

From: Metzger.Autumn@epamail.epa.gov [mailto:Metzger.Autumn@epamail.epa.gov]

Sent: Tuesday, January 22, 2013 6:57 AM

To: Washburn, Bill

Subject: RE: 5905-LOR

Here is the tox memo and scanned version of the label w/my mark ups.

(See attached file: 5905-LOR Acute Tox memo for .2% imidacloprid 1-11-2013.pdf)

(See attached file: 5905-LOR label maked with Agency comments 1-22-2013.pdf)

Autumn Metzger

Biologist

U.S. Environmental Protection Agency

Insecticide-Rodenticide Branch

Registration Division (7505P)

1200 Pennsylvania Ave. NW

Washington, DC 20460

Tel: 703 305-5314

Fax: 703 308-5433

Email: metzger.autumn@epa.gov

"Washburn, Bill" ---01/18/2013 03:47:13 PM---I'll be ready. Thanks,

From: "Washburn, Bill" <WashburnB@helenachemical.com>

To: Autumn Metzger/DC/USEPA/US@EPA

Date: 01/18/2013 03:47 PM

Hi Bill,

I still do not have the product chem review back yet, however I am only going to be in the office 3 more weeks and I'd like to get this label in good shape for the next person if it doesn't get done before I leave. I have the tox review (which I can send you Tue when I'm back in the office) and my label comments.

Let me know if you have some time (probably 20-30 min) to go over this label either tue or wed.

for Tue my availability is: 10-11 am, 1-2 pm or 3-4 pm
wed: so far all day is free except lunch time 12-1.

let me know if you can schedule me in for 30 min in one of those slots.

thanks,

Autumn Metzger
Biologist
U.S. Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (7505P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Tel: 703 305-5314
Fax: 703 308-5433



Email: metzger.autumn@epa.gov005905-00LOR.20130123.Revised Clean Label.pdf



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

FEE

BARCODE: D407176; DECISION NO.: 470337; EPA FILE No.: 5905-LOR;
PRODUCT: PRO-MATE Merit 0.2% With Turf Fertilizer R300

DATE: January 31, 2013

FROM: Akiva Abramovitch, Ph.D.
Technical Review Branch / RD (7505P)

THROUGH: Shyam B. Mathur, Ph.D.
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

Handwritten signature and date:
SB
01-31-13

TO: Autumn Metzger/Venus Eagle, Product Manager, RM 1
Insecticide/Rodenticide Branch / RD (7505P)

SUBJECT: Product Chemistry Review of Pro-Mate Merit 0.2% with Turf Fertilizer

PC CODE: 129099

REGISTRANT: Helena Chemical

USE: Insecticide

INTRODUCTION:

The registrant petitioned to rely on product chemistry data that supports Bayer product EPA Reg. No. 432-1349 Merit 0.2% plus Turf Fertilizer. A statement from Bayer authorizes the use of their data and states that Bayer already provided the formulation process to Helena. In addition, the basic CSF of this pending product dated October 1, 2012 is essentially identical to alternate #3 of EPA Reg. No. 432-1349 Merit 0.2% plus Turf Fertilizer.

CONCLUSIONS:

The TRB has reviewed the product chemistry submission for EPA FILE No.: 5905-LOR, Pro-Mate Merit 0.2% with Turf Fertilizer and has concluded that:

The registrant can rely on the product chemistry data EPA Reg. No. 432-1349 Merit 0.2% plus Turf Fertilizer since the two products use an identical source for the active ingredient and the physical properties of the product will be established primarily by the properties of the fertilizer which is the predominant component in the formulation. Therefore, the CSF basic CSF dated October 1, 2012 is acceptable for the uses listed on the label.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

10/JAN/2013

MEMORANDUM: Acute Toxicity Review for Pro-Mate® Merit 0.2% with Turf Fertilizer

Subject: Name of Pesticide Product: Pro-Mate® Merit 0.2% with Turf Fertilizer
EPA File Symbol: 5905-LOR
DP Barcode: D407177
Decision No.: 470337
Action Code: R300
PC Code: 129099 Imidacloprid

From: Tracy Keigwin, Biologist
Technical Review Branch
Registration Division (7505P)

May Keigwin
Byron T. B...
Jan-11-2013

To: Autumn Metzger, RM 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

Applicant: Carroll Draper, Agent
Helena Chemical Company
7664 Smythe Farm Road
Memphis, TN 38120

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Imidacloprid	0.2

<u>Other Ingredient(s):</u>	<u>99.8</u>
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Total: 100.0%

ACTION REQUESTED: The Risk Manager states: "...This new product is citing a Bayer's product for Acute tox and provided and MRID 42055323. Please review the data and CSF to determine if this acute tox citation supports this new product and the tox language on the proposed label."

BACKGROUND: Helena Chemical Company has submitted an application for the registration of EPA File Symbol 5905-LOR, Pro-Mate® Merit 0.2% with Turf Fertilizer. The proposed product contains 0.2% imidacloprid and fertilizer with applications to turf and ornamentals and has worker protection, commercial and residential use patterns. In support of EPA File Symbol 5905-LOR the registrant has cited MRID 42055323. The cited data was originally submitted to support the registration of EPA Reg. Number 432-1310, Merit 0.62 granular. A search of the OPP electronic files shows that the cited acute toxicity study (MRID 42055323) was waived (HED Records Center; Ottley 11/JAN/1993) and the user was directed to use the data submitted on the 2.5% formulation (EPA Reg. No. 432-1311, Merit 2.5 Greenhouse and Nursery Insecticide; MRIDs 42055324 - 42055329). A search of the OPP electronic files shows that the studies supporting EPA Reg. No. 432-1311 were previously reviewed and (ultimately) found acceptable (HED Records Center; Ottley, 24/MAR/1992; Ottley 11/JAN/1993 and Copley, 28/JUL/1993).

RECOMMENDATIONS:

1. The studies submitted to support EPA Reg. No. 432-1311 are acceptable to support the registration of EPA File Symbol 5905-LOR, Pro-Mate® Merit 0.2% with Turf Fertilizer. The acute toxicity profile of EPA File Symbol 5905-LOR, Pro-Mate® Merit 0.2% with Turf Fertilizer is as follows:

acute oral toxicity	IV	Cited	MRID 42055324
acute dermal toxicity	III	Cited	MRID 42055325
acute inhalation toxicity	IV	Cited	MRID 42055326
primary eye irritation	III	Cited	MRID 42055327
primary skin irritation	IV	Cited	MRID 42055328
dermal sensitization	No	Cited	MRID 42055329

3) The registrant has included some additional precautionary language on the product label. This is acceptable.

4) The proposed Basic CSF submitted for registration must be reviewed and accepted before this product is registered.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for the proposed product as obtained from the Label Review System:

PRODUCT ID #: 5905-591

PRODUCT NAME: Pro-Mate® Merit 0.2% with Turf Fertilizer

PRECAUTIONARY STATEMENTS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear Long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves (such as Natural Rubber, Selection Category A).

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Bayer CropScience



Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**Subject: Letter of Support
Helena Chemical Company; EPA Company No. 5905**

December 3, 2012

Dear Sir/Madam:

Bayer CropScience
P. O. Box 12014
2 TW Alexander Drive
Research Triangle Park
NC 27709
Tel: 919 549-2000


Bayer CropScience LP hereby certifies that based on our contractual agreement, the formulation process in the manufacture of Merit 0.2 Plus Turf Fertilizer (Reg. No. 432-1349) was provided to Helena Chemical Company of 225 Schilling Boulevard, Suite 300, Collierville. This letter is being provided in support of the registration of the Helena Chemical Company product "ProMate Merit 0.2% with Turf Fertilizer

Please do not hesitate to call (919-549-2428) or e-mail me (norma.pangilinan@bayer.com), if you have any questions.

Sincerely,

BAYER ENVIRONMENTAL SCIENCE
A DIVISION OF BAYER CROPSCIENCE

NORMA C. PANGILINAN, Ph.D.,
Registrations Manager

RE: EPA File Symbol. 5905-LOR, Pro-Mate Merit .2% w/turf fertilizer 
Autumn Metzger to: Norma Pangilinan

11/29/2012 11:45 AM

Hi Norma,

Yes, in my previous emails I did clarify that this is not technically an LOA, more of a statement from Bayer that says that the co. has the formulation process.

Autumn Metzger
Biologist
U.S. Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (7505P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Tel: 703 305-5314
Fax: 703 308-5433
Email: metzger.autumn@epa.gov

Norma Pangilinan

Hi Autumn, I was working on revising the LOA a...

11/29/2012 11:41:00 AM

From: Norma Pangilinan <norma.pangilinan@bayer.com>
To: Autumn Metzger/DC/USEPA/US@EPA
Date: 11/29/2012 11:41 AM
Subject: RE: EPA File Symbol. 5905-LOR, Pro-Mate Merit .2% w/turf fertilizer

Hi Autumn,

I was working on revising the LOA and it got me thinking - normally, the purpose of the LOA is to grant authority to the Agency to review our data in the Agency's files in support of the other party's registration application. Considering this, I'm not sure if the statement about the process being known to Helena is appropriate to put in the LOA.

Bayer has patent still in effect with the imidacloprid plus fertilizer process - by our granting them an LOA in support of their registration this signifies that they have knowledge of the Bayer process with our approval.

Is this sufficient to answer the question about the process so we can keep the LOA as is?

Thanks,
Norma

From: Metzger.Autumn@epamail.epa.gov [mailto:Metzger.Autumn@epamail.epa.gov]
Sent: Wednesday, November 28, 2012 4:17 PM
To: Norma Pangilinan
Subject: RE: EPA File Symbol. 5905-LOR, Pro-Mate Merit .2% w/turf fertilizer

Hi Norma,

I had mixed up what I told you on the phone. The product cited is correct (432-1349) which is also a .2%, however the MRID cited for the product chemistry is for 432-1330 (formally 3125-453) and that is a .5%

product. Therefore that MRID is not correct.

Otherwise since you have the basic and the alternate CSF on file for 432-1349, we think it will be ok to use to one you provided 5905-LOR, however we'll have to let PC decide for sure.

As for the LOA, I need the letter to specifically state that Bayer has given Helena the *formulation process*. This proves to product chemistry that they have more than just the MRID numbers, but the actual part of the data needed to make the end-use product identically. I guess its not technically a LOA but rather telling Bayer just telling us that Helena has the actual data and will know how to make the product vs. just the MRIDs to use for data comp purposes.

Last, I was wrong when I thought that this PRIA due date would be in 6-12 months. Its a R300, so the PRIA time frame is only 4 months, putting the PRIA date at 2/25/13. Therefore it may not be possible to approve the sod farm use on this one given the short time left. If the other one gets in quickly we may be able to get it done however it will be close. If someone else stamps it just make sure to forward that to me so we can have it on here since I may not know when that gets approved.

Autumn Metzger
Biologist
U.S. Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (7505P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Tel: 703 305-5314

Fax: 703 308-5433

Email: metzger.autumn@epa.gov

Norma Pangilinan ---11/27/2012 09:03:36 AM---Dear Autumn, To follow-up our phone conversation yesterday, attached please find the revised Letter

From: Norma Pangilinan <norma.pangilinan@bayer.com>
To: "Washburn, Bill" <WashburnB@helenachemical.com>, Autumn Metzger/DC/USEPA/US@EPA
Date: 11/27/2012 09:03 AM
Subject: RE: EPA File Symbol. 5905-LOR, Pro-Mate Merit .2% w/turf fertilizer

Dear Autumn,

To follow-up our phone conversation yesterday, attached please find the revised Letter of Authorization. I hope this now meets the Agency's requirements.

Bill,

Please keep a copy of for your files.

Regards,

Norma

Norma C. Pangilinan, Ph.D.

Registrations Manager; US-Insecticides and Canada



Bayer CropScience

Science For A Better Life
BAYER CROPSCIENCE
BAYER ENVIRONMENTAL SCIENCE
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Tel: 919-549-2428
Mobile: 919-667-8140
Fax: 919-549-3969
E-mail: norma.pangilinan@bayer.com

From: Washburn, Bill [<mailto:WashburnB@helenachemical.com>]
Sent: Monday, November 26, 2012 9:46 AM
To: Norma Pangilinan; metzger.autumn@epa.gov
Subject: FW: EPA File Symbol. 5905-LOR, Pro-Mate Merit .2% w/turf fertilizer

Norma,

Please see the attached e-mail from Autumn Metzger. I am authorizing you to contact Autumn at your earliest convenience to discuss this submission since Bayer supplied all of the information for this package.

Your assistance is very much appreciated.

Regards,

Bill Washburn
Registration Specialist
Helena Chemical Company
901-752-4420

From: Metzger.Autumn@epamail.epa.gov [<mailto:Metzger.Autumn@epamail.epa.gov>]
Sent: Wednesday, November 21, 2012 11:53 AM
To: Washburn, Bill
Cc: Eagle.Venus@epamail.epa.gov
Subject: EPA File Symbol. 5905-LOR, Pro-Mate Merit .2% w/turf fertilizer

Hello Bill,

After reviewing this submission thoroughly, it is decided that we cannot move forward with this application. The main issue is that the product chemistry data that was supplied as a citation is not based on an identical product, which is a requirement. In addition, the data cited is not what is referenced in the

application, cover letter or the LOA from Bayer. Another main issue with the product chemistry is that the Letter of Authorization from Bayer specifically states that the formula and formulation process are confidential from your company. If that is the case, this would not make sense as to you "knowing" their formula or the formulation process - both of which are requirements, unless this was a 100% repack (and then of course no data is required). In the future, if product chemistry is going to be cited the LOA must state that you are fully aware of both the formula and the formulation process.

Another issue noted is that sod farms are not supported via formulator's exemption for the MUP listed. It is not listed on that label and therefore would need to be removed from your label or if allowed by the MUP supplemented with an additional data citation and offer to pay.

At this time we ask that you withdraw this application in writing (email is fine) as we cannot grant, or even move forward with it. Please feel free to contact myself or the product manager, Venus Eagle with further questions.

Autumn Metzger
Biologist
U.S. Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (7505P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Tel: 703 305-5314
Fax: 703 308-5433
Email: metzger.autumn@epa.gov

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

(See attached file: LOA for Helena_26Nov2012.pdf)

11/28/12 lots of Bact & fort. w/Bayer
& all is covered.

EPA File Symbol. 5905-LOR, Pro-Mate Merit .2% w/turf fertilizer
Autumn Metzger to: WashburnB
Cc: Venus Eagle

11/21/2012 12:53 PM

PRIA 2/25/13

Hello Bill,

After reviewing this submission thoroughly, it is decided that we cannot move forward with this application. The main issue is that the product chemistry data that was supplied as a citation is not based on an identical product, which is a requirement. In addition, the data cited is not what is referenced in the application, cover letter or the LOA from Bayer. Another main issue with the product chemistry is that the Letter of Authorization from Bayer specifically states that the formula and formulation process are confidential from your company. If that is the case, this would not make sense as to you "knowing" their formula or the formulation process - both of which are requirements, unless this was a 100% repack (and then of course no data is required). In the future, if product chemistry is going to be cited the LOA must state that you are fully aware of both the formula and the formulation process.

Another issue noted is that sod farms are not supported via formulator's exemption for the MUP listed. It is not listed on that label and therefore would need to be removed from your label or if allowed by the MUP supplemented with an additional data citation and offer to pay.

At this time we ask that you withdraw this application in writing (email is fine) as we cannot grant, or even move forward with it. Please feel free to contact myself or the product manager, Venus Eagle with further questions.

Autumn Metzger
Biologist
U.S. Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (7505P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Tel: 703 305-5314
Fax: 703 308-5433
Email: metzger.autumn@epa.gov

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 10-2-12

Experts In-Processing Signature: B.B.

Date 10-4-12

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>5905-LOR</u>		EPA Receipt Date: <u>10-2-12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)			X
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * A.I - 1 % Comp added.
- * CSF : Approved for non-food use in
- * Xlb Data Submitted. Requested is cefny
- * Tackel approved.

MRID: X/A

1K 5-#813

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 3, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-470337
EPA File Symbol or Registration Number: 5905-LOR
Product Name: PRO-MATE MERIT 0.2% WITH TURF FERTILIZER
EPA Receipt Date: 02-Oct-2012
EPA Company Number: 5905
Company Name: HELENA CHEMICAL CO

BILL WASHBURN
HELENA CHEMICAL CO
225 SCHILLING BOULEVARD, SUITE 300
COLLIERVILLE, TN 38017

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300

NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in cursive script, appearing to read "Teresa Jones", is written over the typed name.

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

W
{924765E~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

1

Receipt No.

S-

924765

EPA File Symbol/Reg. No.

5905-LOR

Pin-Punch Date:

10/2/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R300

Granted:

R300

Amount Due: \$ 1434.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: W. Miller

Date: 10/3/12

Remarks:

Receipt for Section 3

S: 924765

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 5905 HELENA CHEMICAL CO

V

Risk Manager: Registration Division, Risk Management Team 1

Product #: 5905-LOR Product Name: PRO-MATE MERIT 0.2% WITH TURF FERTILIZ

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 01-Oct-2012

OPP Rec'd Date: 02-Oct-2012

Front End Date: 02-Oct-2012

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

NEW REGISTRATION

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

CSF

Paper Label

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:



HELENA CHEMICAL COMPANY

225 Schilling Blvd., Suite 300
Collierville, Tennessee 38017
Telephone: 901-761-0050

FedEx Tracking Number
7990 7610 6905

September 28, 2012

Environmental Protection Agency
Washington Finance Center
FIFRA Service Fees
P.O. Box 979074
St. Louis, MO 63197-9000

Subject: Registration Service Fee

PRO-MATE MERIT 0.2% WITH TURF FERTILIZER
EPA Reg. No. 5905-Unassigned

Dear Sir/Madam:

Please find enclosed Helena Chemical's check number 2231912 in the amount of \$1,434.00. This covers the service fee for EPA Registration Category R300. A copy of the Application for Pesticide Registration, Form 8570-1, is enclosed to support the justification for this Category.

If you have any questions in regards to this submission, please do not hesitate to contact me at 901-752-4420 or by e-mail at washburnb@helenachemical.com.

Sincerely,

A handwritten signature in cursive script that reads "Bill Washburn".

Bill Washburn
Registration Specialist

No. 2231912

DATE: 27-SEP-12

VENDOR NAME

US EPA WASHINGTON FI VENDOR NO. 72862

[illegible]

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT.

Thank You

0.00

1.434.00



HELENA CHEMICAL COMPANY

225 SCHILLING BLVD., SUITE 300
COLLIERVILLE, TN 38017

MELLON BANK, N.A.
Pittsburgh, PA

No. 2231912

60-160
433

CHECK DATE	CHECK NUMBER	CHECK AMOUNT
27-SEP-12	2231912	*****1,434.00

PAY	One Thousand Four Hundred Thirty-Four Dollars And 00 Cents***.***.***	ACCOUNTS PAYABLE
-----	-----------------------------------------------------------------------	------------------

TO
THE
ORDER
OF

US EPA WASHINGTON FINANCE CENTER
US BANK - GVMT LOCKBOX 979074
1005 CONVENTION PLZ
SL-MO-C2-GL
ST LOUIS, MO 63197

82

2roy 2royP/

NOT VALID AFTER 180 DAYS

11000223191211

Washburn, Bill

From: trackingupdates@fedex.com
Sent: Monday, October 01, 2012 9:48 AM
To: Washburn, Bill
Subject: FedEx Shipment 799076106905 Delivered

This tracking update has been requested by:

Company Name: Helena Chemical Company
Name: Bill Washburn
E-mail: washburnb@helenachemical.com

Our records indicate that the following shipment has been delivered:

Reference: PROMATE MERIT WTF
Ship (P/U) date: Sep 28, 2012
Delivery date: Oct 1, 2012 9:43 AM
Sign for by: M.EBEL
Delivery location: SAINT LOUIS, MO
Delivered to: Mailroom
Service type: FedEx Standard Overnight
Packaging type: FedEx Envelope
Number of pieces: 1
Weight: 0.50 lb.
Special handling/Services: Deliver Weekday
Tracking number: 799076106905

Shipper Information	Recipient Information
Bill Washburn	GOVERNMENT LOCKBOX 979074
Helena Chemical Company	U.S. BANK - EPA WASHINGTON
7664 Smythe Farm Road	FINANCE
Memphis	1005 CONVENTION PLZ
TN	SL-MO-C2-GL
US	SAINT LOUIS
38120	MO
	US
	63101

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<div style="display: inline-block; vertical-align: middle;"> EPA United States Environmental Protection Agency Washington, DC 20460 </div>		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other:	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 5905-xxx		2. EPA Product Manager Venus Eagle	
4. Company/Product (Name) Pro-Mate Merit 0.2% with Turf Fertilizer		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Helena Chemical Company 225 Schilling Boulevard, Suite 300 Collierville, TN 38017 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>432-1349</u> Product Name <u>Merit 0.2 Plus Turf fertilizer Insecticide</u>	
Section - II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> "Me Too" Application <input type="checkbox"/> Notification - Explain below. <input type="checkbox"/> Other - Explain below			
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) PRIA Category: R 300 Justification: New product; "Me-too"; identical in composition and use to a registered product; selective data citation where applicant submits specific authorization letter from data owner. Contact: Bill Washburn E-mail: washburnb@helenachemical.com			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Package wgt. container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 30 lbs, 40 lbs, 50 lbs, 1000 lbs	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other <u>booklet in glued pouch with base label</u> <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name BILL WASHBURN		Title REGISTRATION SPECIALIST	
		Telephone No. (Include Area Code) 901-752-4420	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title REGISTRATION SPECIALIST	
4. Typed Name BILL WASHBURN		5. Date 10/01/2012	



United States Environmental Protection Agency
Washington, D.C. 20460

Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Helena Chemical Company 225 Schilling Blvd., Suite 300 Collierville, TN 38017	EPA File Symbol/Registration Number 5905-xxx
	Product Name Pro-Mate Merit 0.2% with Turf Fertilizer
	Date of Confidential Statement of Formula (EPA Form 8570-4) 10/01/2012

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s): **Imidacloprid**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:





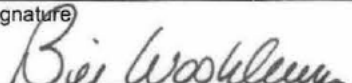
(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR



(B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Imidacloprid		
Signature 	Name and Title Bill Washburn, Registration Specialist	Date October 1, 2012

EPA Form 8570-27 (Rev. 7-91)

White - EPA copy

Yellow - Applicant copy

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number Helena Chemical Co., 225 Schilling Blvd., Suite 300, Collierville, TN 38017	EPA Registration Number/ File Symbol 5905-xxx
Active Ingredient(s) and/or representative test compound(s): Imidacloprid	Date October 1, 2012
General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial, non-food crop, domestic, outdoor	Product Name Pro-Mate Merit 0.2% with Turf Fertilizer

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

- ☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

- ☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).
- ☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

- ☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Bill Washburn</i>	Date 10/01/2012	Typed or Printed Name and Title Bill Washburn, Registration Specialist
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Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Reg. No.	Date Submitted to EPA	Electronic file name
5905-xxx	10/01/2012	005905-00xxx.20121001.ProMate Merit 0.2% WTF

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.


Signature

October 1, 2012
Date

Bill Washburn
Name (typed)

Registration Specialist
Title

Bayer CropScience



Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Letter of Authorization
Helena Chemical Company; EPA Company No. 5905

November 26, 2012

Dear Sir/Madam:

Bayer CropScience
P. O. Box 12014
2 TW Alexander Drive
Research Triangle Park
NC 27709
Tel: 919 549-2000

Bayer CropScience LP hereby authorizes the U.S. Environmental Protection Agency, Office of Pesticide Program to refer to any research and test data in the Agency's files on our active ingredient Imidacloprid and on our product Merit 0.2 Plus Turf Fertilizer (Reg. No. 432-1349) in support of the registration of "ProMate Merit 0.2% with Turf Fertilizer" by Helena Chemical Company of 225 Schilling Boulevard, Suite 300, Collierville, TN.

These data include (but are not limited to) the following:

<u>Study Type</u>	<u>MRID No.</u>
Analytical Method/Physical & Chemical Properties/Storage Stability & Corrosion Characteristics	43240701
Acute Oral Toxicity/Acute Dermal Toxicity/ Acute Inhalation Toxicity/Primary Eye Irritation Primary Skin Irritation/Dermal Sensitization	42055323

This authorization is granted only to the applicant named above and only for the specific active ingredient and product described above. This authorization may not be transferred by the applicant named above in any manner whatsoever, without the written prior consent of BAYER. This authorization may not be used to support registration of a manufacturing use product. This authorization will expire on September 14, 2014. Further use of the data will require authorization by Bayer.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date October 1, 2012	EPA Reg. No./File Symbol 5905-xxx	Page 1 of 2
Applicant's/Registrant's Name & Address: Helena Chemical Co., 225 Schilling Blvd., Suite 300, Collierville, TN 38017		Product Pro-Mate Merit 0.2% with Turf Fertilizer

Ingredient(s): **Imidacloprid, CAS No. 138261-41-3**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Product Chemistry

830.1550	Product Identity and Composition	See CSF			
830.1600	Description of the Materials Used to Produce the Product	See CSF			
830.1650	Description of the Manufacturing Process	See CSF			
830.1670	Discussion of Formation of Impurities	43240701	Bayer Environmental Science	PER	
830.1700	Preliminary Analysis	43240701	Bayer Environmental Science	PER	
830.1750	Certified Limits	See CSF	Bayer Environmental Science	PER	
830.1800	Enforcement Analytical Method	43240701	Bayer Environmental Science	PER	
830.6302	Color	43240701	Bayer Environmental Science	PER	
830.6303	Physical State	43240701	Bayer Environmental Science	PER	
830.6304	Odor	43240701	Bayer Environmental Science	PER	
830.7200	Melting Point				N/A – end use product
830.7220	Boiling Point				N/A – end use product
830.7300	Density/Relative Density/Bulk Density	43240701	Bayer Environmental Science	PER	
830.7840	Solubility (Column elution/shake flask)				N/A – end use product
830.7950	Vapor Pressure				N/A – end use product
830.7370	Dissociation Constant				N/A – no oxidation or reduction characteristics
830.7570	Partition Coefficient				N/A – end use product
830.7000	pH	43240704	Bayer Environmental Science	PER	
830.6313	Stability				N/A – end use product
830.6314	Oxidation/Reduction: Chemical Compatibility				
830.6315	Flammability				N/A – end use product
830.6316	Explosibility				N/A – end use product
830.6317	Storage Stability	43240701	Bayer Environmental Science	PER	
830.7100	Viscosity				N/A – solid material
830.6319	Miscibility				N/A – solid material
830.6320	Corrosion Characteristics	43240701	Bayer Environmental Science	PER	
830.6321	Dielectric Breakdown Voltage				N/A – not for use around electrical equipment

Signature 	Name and Title: Bill Washburn, Registration Specialist	Date 10/01/2012
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